(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 208 814 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
29.05.2002 Bulletin 2002/22

(51) Int Cl.[7]: **A61F 2/06**

(21) Application number: **01123460.6**

(22) Date of filing: **28.09.2001**

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **13.10.2000 US 687455**

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(54) Low profile stent

(57) A stent having a hollow, cylindrical body 7 made with a plurality of rings 10. The rings each extend circumferentially around the cylindrical body and include an undulating series of angulated peaks 11 and valleys 12. The rings are joined together by a series of links 15, the rings and links being shaped and arranged to promote a very low compressed profile and longitudinal flexibility during stent delivery on the catheter and effective scaffolding after deployment. The rings are provided with inflection points 21 on some portions of the rings which extend in a generally circumferential direction for a short distance.

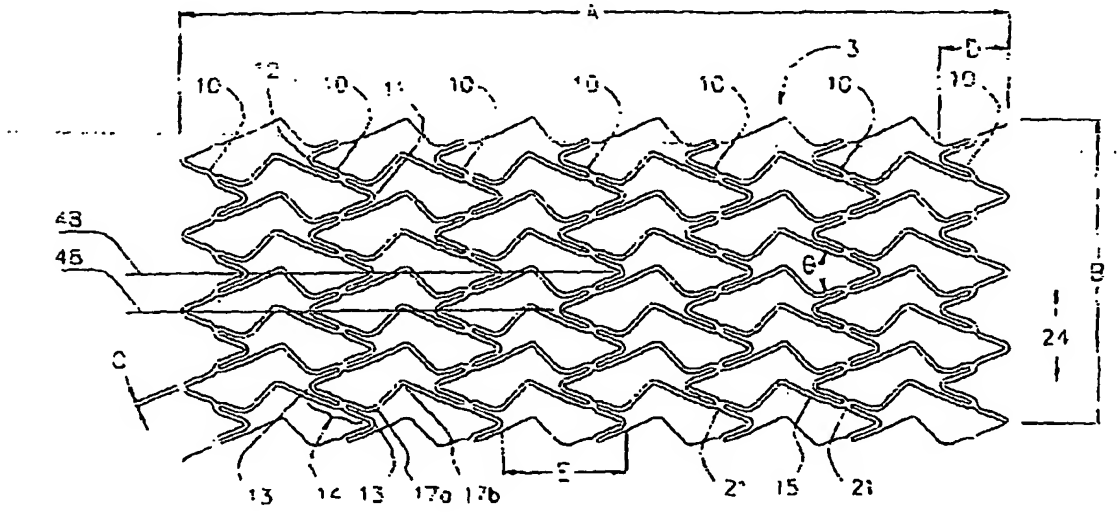

FIG. 2

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Description

[0001] The invention relates to intraluminal endovascular stenting, and in particular, to a low profile stent.

[0002] Endovascular stenting is particularly useful for arteries which are blocked or narrowed and is an alternative to surgical procedures that intend-to bypass the occlusion. The procedure involves inserting a prosthesis into a body lumen and expanding it to prevent collapse of a vessel wall. While stenting has most commonly been used adjunctively, following an intervention such as angioplasty or atherectomy, there is increasing interest in primary, or direct stent placement.

[0003] Percutaneous transluminal coronary angioplasty (PTCA) is used to open coronary arteries which have been occluded by a build-up of cholesterol fats or atherosclerotic plaque. Typically, a guide catheter is inserted into a major artery in the groin and is passed to the heart, providing a conduit to the ostia of the coronary arteries from outside the body. A balloon catheter and guidewire are advanced through the guiding catheter and steered through the coronary vasculature to the site of therapy. The balloon at the distal end of the catheter is inflated, causing the site of the stenosis to widen. The dilatation of the occlusion, however, can form flaps, fissures and dissections which threaten re-closure of the dilated vessel or even perforations in the vessel wall. Implantation of a stent can provide support for such flaps and dissections and thereby prevent reclosure of the vessel or provide a patch repair for a perforated vessel wall until corrective surgery can be performed. Reducing the possibility of restenosis after angioplasty reduces the likelihood that a secondary angioplasty procedure or a surgical bypass operation will be necessary.

[0004] A stent is typically a cylindrically shaped device formed from wire(s) or a tube and is intended to act as a permanent prosthesis. A stent is deployed in a body lumen from a radially compressed configuration into a radially expanded configuration which allows it to contact and support a body lumen. The stent can be made to be radially self-expanding or expandable by the use of an expansion device. The self expanding stent is made from a resilient springy material while the expandable stent is made from a material which is plastically deformable. A plastically deformable stent can be implanted during an angioplasty procedure by using a balloon catheter bearing a crimped, or compressed stent which has been loaded onto the balloon. The stent radially expands as the balloon is inflated, forcing the stent into contact with the body lumen thereby forming a supporting relationship with the vessel walls. Deployment is effected after the stent has been introduced percutaneously, transported transluminally and positioned at a desired location by means of the balloon catheter.

[0005] A balloon of appropriate size and pressure is first used to open the lesion. The process can be repeated with a stent loaded onto a balloon. Direct stenting involves simultaneously performing angioplasty and stent implantation using a stent mounted on a dilatation balloon. The stent remains as a permanent scaffold after the balloon is withdrawn. A balloon capable of withstanding relatively high inflation pressures may be preferable for stent deployment because the stent must be forced against the artery's interior wall so that it will fully expand, thereby precluding the ends of the stent from hanging down into the channel, encouraging the formation of thrombus.

[0006] In adjunctive stenting, a stent delivery system with a small diameter profile is not required because the narrowing has already been enlarged by the preceding device. However, in direct stenting, the stent and delivery balloon catheter need to be inserted into a stenosis that has not been previously dilated. Thus, for direct stenting to be applicable to many patients, the stent and delivery system must have a very low profile. The primary advantage of direct stenting is the procedural efficiency gained by eliminating a primary angioplasty step. The resulting procedure can be shorter and less expensive.

[0007] Primary angioplasty followed by stent placement typically requires a catheter exchange, which is usually performed over a guidewire. Given the prevalence of this staged procedure, the most commonly used balloon catheters have been over-the-wire types, having either a full length guidewire lumen or a short, distal guidewire lumen as found in rapid exchange catheters. Fixed wire, or "balloon-on-a-wire" type balloon catheters have been seldom used for primary angioplasty in stenting procedures, and these catheters have not been used to deliver stents at all. With their small size and wire-like trackability, fixed wire catheters are able to provide relatively quick and simple balloon placement and access to lesions that cannot be reached with other types of catheters. The small size of fixed wire catheters also permits their use through very small guiding catheters. However, these balloon catheters lack the ability to maintain guidewire position across a lesion for exchange purposes and they may encounter problems re-crossing a dilated area. Another reason that fixed wire balloon catheters have not been used for stent delivery is that the very small deflated profile of the balloon on such a catheter may be too small to securely carry a compressed stent of conventional design.

[0008] Previous structures used as stents or intraluminal vascular grafts have included coiled stainless steel springs; helical wound spring coil made from shape memory alloy; expanding metal stents formed in a zig-zag pattern; diamond shaped, rectangular shaped, and other mesh and non-mesh designs. Exemplary stent devices are disclosed in U.S. Patent 5,776,161 issued to Globerman, U.S. Patent 5,449,373 issued to Pinchasik et al, U.S. Patent 5,643,312 issued to Fischell et al and U.S. Patent 5,421,955 issued to Lau et al.

[0009] Problems to be overcome in stent design include inadequate radial force to maintain expansion; inadequate scaffolding of tissue to the wall; pre-dilated

longitudinal rigidity which negatively impacts on stent delivery; and shortening of the stent as a consequence of radial expansion. Predilation stent longitudinal rigidity is a significant shortcoming, and prevents the threading of the stent through long tortuous vessels and lesions. Shortening of the stent is also a problem, as it is important that the stent cover the entire lesion to minimize the risk of post-operative complications. Many of these problems are the result of difficult design problems resulting from the often conflicting goals of stent design. For example, it is desirable to have a high degree of scaffolding in the stent when the stent is expanded to its rated radial size so that the vessel wall will have uniform support. However, it is also desirable to have a small, relatively smooth delivered profile when the stent is mounted on the catheter to permit the stent and catheter to traverse small diameter lesions. The person skilled in the art will appreciate that, as a stent with a very small delivered profile expands radially, its structural elements become farther apart and create openings which reduce the amount of scaffolding available to support the vessel. A similar situation exists with respect to the conflicting goals of improved scaffolding and flexibility during catheter delivery since proper scaffolding will not be accomplished if there are few supporting structural elements and yet a stent with too many structural elements may be difficult to crimp small enough to fit onto the balloon catheter such that the structural elements will not abut or interfere with each other during delivery through tortuous vessels. Also, in some stents, during plastic deformation of the stent (i.e. balloon expansion) the strain is concentrated at small zones. This limits the properties of the material that can be used as well as the radial force and the expansion rate.

[0010] U.S. Patent number 6,090,127 addresses a number of these issues. The '127 patent discloses an expandable stent having a small initial diameter, flexibility along its longitudinal axis prior to expansion and minimization of rigid local strain on the stent material by the presence of rotation joints which have minimal strain during stent expansion. The stent is substantially the same length before and after expansion and being flexible longitudinally when constrained, it is easy to deliver. However, the delivery of such a stent on very low profile, fixed wire delivery catheters requires additional improvements in the size of the minimal crimped diameter.

[0011] The present invention, according to one aspect, provides an endovascular stent comprising:

a hollow cylindrical body comprised of a first ring and a second ring, each of the rings having a width and extending circumferentially around the cylindrical body, each ring including an undulating series of peaks and valleys formed by opposing angled segments joined to each other by straight segments;

an inflection point interrupting at least one straight segment on each of the rings to produce a generally circumferential offset therein;

an asymmetrical link joining the first and second rings by extending between the inflection points thereon, the link having a width substantially equal to the width of the rings and having a central angle and substantially equal length end segments extending therefrom, one end segment being substantially straight and the other end segment including an angle nearly equal to the central angle, the end segment angle bending in the opposite direction from the central angle.

[0012] According to another aspect, the invention provides an endovascular stent having a nominal expanded diameter and, as manufactured from a cylindrical tube, the stent comprises:

a first ring and a second ring, each of the rings extending circumferentially around the cylindrical tube in an undulating series of peaks and valleys formed by opposing angled segments joined to each other by straight struts, and each strut having parallel first and second limbs extending from each end of the strut to a central orthogonal joint, the first limb being joined to one of the angled segments at each end of the strut;

an asymmetrical link connecting the first and second rings by extending between one of the second limbs in the first ring and one of the second limbs in the second ring, the link having a first angle located centrally between the first and second rings, one end of the link being substantially aligned with the second limb in the first ring, the other end of the link having a second angle where it joins the second limb of the second ring, the second angle being about equal to the first angle, the end segment angle bending in the opposite direction from the central angle.

[0013] The stent of the present invention has a hollow, cylindrical body made with a plurality of rings. It is manufactured from tubing having a diameter between the minimal crimped diameter of the stent and the nominal size which is closely matched to the size of the vessel to be treated. In the manufactured form of the stent, the rings each extend circumferentially around the cylindrical body and include an undulating series of peaks and valleys. The undulating peaks and valleys of the rings are preferably formed by opposing angled segments joined to each other by substantially straight struts. The rings are joined together by a series of links which are shaped and arranged to promote longitudinal flexibility as the stent is delivered on the catheter and effective scaffolding after deployment and to prevent shortening of the stent as the stent is expanded.

[0014] Preferably, the rings are provided with orthogonal joints, or inflection points on the struts which extend

between an adjacent peak and valley of the ring. At each inflection point, a portion of the ring extends in a generally circumferential direction for a short distance, producing an offset in the otherwise straight struts. Typically, the inflection point is substantially centered between a peak and a valley of the ring. A link is joined at one end at the inflection point on one ring and also joined at a second end at a second inflection point on an adjacent ring. Preferably, the link includes at least two angled segments in the unexpanded device which are capable of deflecting to promote the tendency of the stent to flex longitudinally when it is subjected to bending forces such as those encountered during delivery of the stent and catheter through a tortuous vascular anatomy. Also preferably, the short portion of the ring at the inflection point which extends generally circumferentially has a length measured circumferentially which is at least as great as the width of the link to which it is attached. Preferably, the circumferential length is no more than about twice the width of the link to which it is attached. This promotes the scaffolding provided to the vessel by the expanded stent since the links can be fit together closely in a nested arrangement with the undulations of the rings as the stent is crimped on the balloon catheter. By "nest", "nested" or nesting" herein we mean that the elements are conformally arranged such they can be in very close proximity when the stent is crimped and loaded onto a catheter but without substantial contact that would affect the ability of the various elements to move in relation to each other as the stent and catheter are advanced through a tortuous body vessel. In some preferred embodiments of-the invention, no more than one link is connected to either of the first and second inflection points. This makes the inflection point a "dead end" in the longitudinal extent of the connecting links for the stent and permits some of the flexing forces which are not absorbed by the link itself to be absorbed by the rings to which it is attached. The links are arranged to provide flexibility and the peaks and valleys of the rings are paired with each other in an in-phase relationship. Preferably, the rings are joined by multiple links (most preferably 3 or more) and have the same number of inflection points on each ring as the number of attaching links. When a large number of connecting links are employed, the angles in the links are preferably of a complimentary shape to each other such that they will nest together when the stent is crimped for mounting onto the catheter.

[0015] Another feature of the preferred embodiments is the conformal nesting of ring and link components such that the stent can be readily crimped for loading onto a balloon or other expansion device on the catheter. The stent made according to the present invention may be made from a tube which is cut with lasers or other techniques which are well known to those skilled in the art. The initial pattern cut into the tube includes link and ring components which cooperate with each other but which provide sufficient spacing between components that the stent can be crimped onto a catheter without causing general abutment of the ring and link components with each other and also permit longitudinal movement of the link components without disturbing the crimp of the ring components on the catheter during deployment of the stent through tortuous coronary arteries. The need for spacing between the components in the crimped condition must be balanced with the need to provide improved scaffolding of the vessel being treated. A relatively abundant number of links provides improved scaffolding of the vessel but potentially interferes with the ability to crimp the stent onto the catheter.

[0016] Yet another feature of the preferred embodiments is in connection with the stent configuration in which the undulating peaks and valleys of the rings are oriented such that the rings have peaks and valleys which are paired with each other in an in-phase relationship. In such a configuration, a link can be provided which interconnects with the rings at points on the rings which are substantially centered between the respective peaks and valleys of the rings and yet allows the link to nest within the peaks and valleys of the rings. This can be accomplished by providing at least two angled segments in the link in a central portion of the link.

[0017] In the manufactured form of the preferred embodiments, using relatively sharp angled bends instead of gentle curves and placing adjacent portions of links and rings close together can provide the spacing needed for more compact nesting of the ring and link components which allows the compressed stent to be securely mounted onto a very low profile, fixed wire catheter. A further aid in reducing the minimal crimp diameter of the stent is to make the rings and links as narrow as possibly permitted by other design constraints. Thus, in the present invention, large numbers of connecting links can be included within a stent design having a very low minimal crimp diameter.

[0018] Preferred embodiments will now be described, by way of example only, with reference to the drawings.

[0019] Figure 1 is a side view of a stent according to the present invention on a delivery catheter.

[0020] Figure 2 is a plan view showing an opened and flattened stent made according to the present invention.

[0021] The stent 3 of the present invention and shown in figure 1 on delivery catheter 5 has a hollow, cylindrical body 7 made with a plurality of rings, one of which is designated 10. This stent 3 can be made by laser cutting from a tube of stainless steel or other suitable material by methods which are well known by those skilled in the art. As shown in Figure 2, the stent 3 has been cut open longitudinally and laid flat for convenience in description. It is shown as it would appear after manufacture, in an uncrimped and unexpanded condition. Each of the rings 10 extend circumferentially around the cylindrical body of the stent 3 and include an undulating series of peaks 11 and valleys 12. The undulating peaks 11 and valleys 12 of the rings 10 are formed by opposing angled segments 13 joined to each other by substantially

straight struts 14. Adjacent rings 10 are joined together in a repeating pattern by a series of asymmetrical links 15 which are shaped and arranged to promote a very low crimp diameter, as well as longitudinal flexibility during delivery and effective scaffolding after deployment. It should be noted that the configuration of the rings 10 are oriented such that the rings have undulating peaks 11 and valleys 12 which are paired with each other in an in-phase relationship. Figure 2 shows longitudinal axes 48, extending through adjacent peaks 11 and valleys 12 of rings 10. A link 15 is provided which interconnects with the rings 10 at orthogonal joints, or inflection points 21.

[0022] The inflection points 21 are shown substantially centered on struts 14 between a peak and a valley of the rings 10. At each inflection point 21, a portion of the ring extends in a generally circumferential direction (indicated generally 24) for a short distance, resulting in an offset in the otherwise straight strut 14. The end portions of links 15 are arranged closely parallel to struts 14, and the links are joined to opposite sides of inflection points 21, forming a central orthogonal joint in strut 14. As an alternative description of the same structure, each strut 14 may be considered as including two parallel limbs extending from a central inflection point 21, and having the end of each limb connected to either a link 15 or an angled segment 13 forming a peak 11 or a valley 12. In strut 14, the parallel limbs that connect to links 15 are diagonally opposed to each other across the orthogonal joint, or inflection point 21. The limbs are narrow and formed closely parallel to each other to make the overall width of strut 14 as narrow as possible.

[0023] Figure 2 depicts a cut open stent that has been manufactured according to the present invention and can expand to become a nominal size of 2.5 mm diameter and 15 mm length. In this example, the stent was cut from metal tubing of about 1.7 mm diameter. Preferably, as shown in this example, the tubing selected for making the stent has a diameter measuring about 70% of the nominal, expanded stent diameter. With this proportion between the diameters of expanded stent and the tubing from which it is made, the narrow struts 14 and sharply angled bends 13 combine to yield an angle θ between adjacent struts14 that generally exceeds 40E. In the example shown in Figure 2, θ measures 42E. By forming peaks 11 and valleys 12 with angled bends 13 instead of broader curves, struts 14 can be deformed closely parallel to each other when peaks 11 and valleys 12 are compressed. When the stent 3 is compressed, the narrowness of the struts 14 and their close compressed arrangement provides a smaller crimped circumference (and diameter) than was achieved in previous stents.

[0024] A link 15 is joined at one end at the inflection point 21 on ring 10 and is joined at the other end at another inflection point 21 on an adjacent ring 10. Each link 15 includes at least two angled segments 17a-b in the unexpanded stent 3 which promote the ability of the stent 3 to flex longitudinally when it is subjected to bending forces such as those encountered during delivery of the stent 3 on a catheter through a tortuous coronary artery. In the present invention, link 15 is made as short as possible to reduce the amount of material to be crimped into a small diameter without compromising flexibility and scaffolding properties. In order to reduce the length of links 15, segments 17a-b are formed with angles greater than about 90E, and these segments are confined, generally, between adjacent longitudinal axes 48. Only angled segment 17b extends across an axis 48, by approximately the width of link 15. Angled segments 17a-b, like angled segments 13, are formed as tight angled bends instead of broader curves to promote compression to smaller diameters. Angled segment 17b of link 15 is located centrally between adjacent rings 10, and one end of link 15 includes angled segment 17a, while the other end extends in a substantially straight line from angled segment 17b to its connection at an inflection point 21.

The connecting links 15 are positioned such that when the stent 3 is expanded they will extend outward from the inflection point 21 and assist in the scaffolding provided by the central portion of the ring 10. The connecting links 15 also extend past the peak 11 or valley 12 components to extend the scaffolding provided by the peak 11 and valley 12 components of the rings 10 toward the next ring. Circumferentially adjacent asymmetrical links 15 are longitudinally reversed with respect to each other. This means that if angled segment 17a is to the right of angled segment 17b in one link 15, then the links 15 immediately above and below that link 15 have angled segment 17a to the left of angled segment 17b. Notice that angled segment 17a bends in the opposite direction from angled segment 17b, and both segments 17a-b preferably have the same angle. The above shapes and arrangement of rings 10 and links 15 provide relatively large "cell" size (i.e. the size of the smallest repeating unit in the pattern) to provide more space for elements to move into during compression of the stent, thus permitting a very low crimped profile.

[0025] The stent 3 has a length "A" which can be about 8 to 30 mm (and as depicted could be about 15-25) mm for a coronary artery application although those skilled in the art will appreciate that the pattern can be configured to give many lengths. The dimension "B" refers to the uncrimped circumference of the stent 3, as manufactured for a coronary artery application which can be about 3-7 mm and gives a diameter for the stent 3 of about 1-2 mm. In the preferred embodiment, rings 10 and links 15 have the same width "C", which can be in the range of about 0.04 to 0.10 mm, and preferably is about 0.065 mm. The dimension "D" refers to the amplitude of one of the rings and in this example could be in the range of about 0.75 to 2.5 mm. The dimension "E" refers to the peak-to-peak spacing for the rings and in this example could be in the range of about 1-3 mm. The preferred spacing between the parallel

limbs of strut 14 is less than 0.10 mm, more preferably about 0.084 mm. Using the preferred dimensions given above, and the preferred selection of four peaks 11 per ring 10, the 2.5 mm diameter stent in this example can achieve a minimal crimped diameter of about 0.74 mm (0.029 in.). This very low crimped profile is obtained by the present invention without compromising other important design features, such as longitudinal flexibility of the compressed stent, or the scaffolding strength of the final, expanded stent.

Claims

1. An endovascular stent comprising:

   a hollow cylindrical body (7) comprised of a first ring (10) and a second ring, each of the rings having a width and extending circumferentially around the cylindrical body, each ring (10) including an undulating series of peaks (11) and valleys (12) formed by opposing angled segments (13) joined to each other by straight segments(14);
   an inflection point (21) interrupting at least one straight segment on each of the rings to produce a generally circumferential offset therein;
   an asymmetrical link (15) joining the first and second rings (10) by extending between the inflection points thereon, the link having a width substantially equal to the width of the rings and having a central angle and substantially equal length end segments extending therefrom, one end segment being substantially straight and the other end segment including an angle nearly equal to the central angle, the end segment angle bending in the opposite direction from the central angle.

2. The stent of claim 1 wherein each of the angled segments (13) of the rings (10) has an included angle of at least about 40E.

3. The stent of claim 1 or 2 wherein the inflection point (21) is substantially centered between a peak (11) and a valley (12).

4. The stent of claim 1, 2 or 3 wherein the first and second rings each include the same number of inflection points (21).

5. The stent of any preceding claim wherein the peaks of the first ring are aligned on common longitudinal axes with the valleys of the second ring, and the valleys of the first ring are aligned on common longitudinal axes (48) with the peaks of the second ring.

6. An endovascular stent having a nominal expanded diameter and, as manufactured from a cylindrical tube (7), the stent comprises:

   a first ring and a second ring (10), each of the rings extending circumferentially around the cylindrical tube in an undulating series of peaks (11) and valleys (12) formed by opposing angled segments (13) joined to each other by straight struts (14), and each strut having parallel first and second limbs extending from each end of the strut to a central orthogonal joint (21), the first limb being joined to one of the angled segments at each end of the strut;
   an asymmetrical link (15) connecting the first and second rings (10) by extending between one of the second limbs in the first ring and one of the second limbs in the second ring, the link having a first angle located centrally between the first and second rings, one end of the link being substantially aligned with the second limb in the first ring, the other end of the link having a second angle where it joins the second limb of the second ring, the second angle being about equal to the first angle, the end segment angle bending in the opposite direction from the central angle.

7. The stent of any preceding claim wherein the first and second rings (10) are joined by a plurality of the links (15).

8. The stent of claim 7 wherein circumferentially adjacent links are longitudinally reversed with respect to each other.

9. The stent of any preceding claim wherein the link (15) lies completely between adjacent longitudinal axes joining peaks (11) and valleys (12).

10. The stent of any preceding claim wherein the link (15) extends beyond one of the adjacent longitudinal axes by no more than the width of the link.

11. The stent of claim 6 or any of claims 7 to 10 when dependent thereon, wherein the tube has a diameter that is approximately 70% of the nominal diameter of the stent, and each of the angled segments of the rings has an included angle of at least about 40E.

12. The stent of claim 6 or any of claims 7 to 11 when dependent thereon, wherein the first and second rings each include the same number of orthogonal joints (21).

13. The stent of claim 6 or any of claims 7 to 12 when dependent thereon, wherein each of the first limbs

on the ends of each strut are offset extensions of each other through the orthogonal joint (21) of the strut (14).

14. The stent of claim 6 or any of claims 7 to 13 when dependent thereon, wherein the peaks of the first ring are aligned on common longitudinal axes with the valleys of the second ring, and the valleys of the first ring are aligned on common longitudinal axes with the peaks of the second ring.

15. The stent of claim 6 or any of claims 7 to 14 when dependent thereon, wherein the angled segments, limbs and links all have the same width.

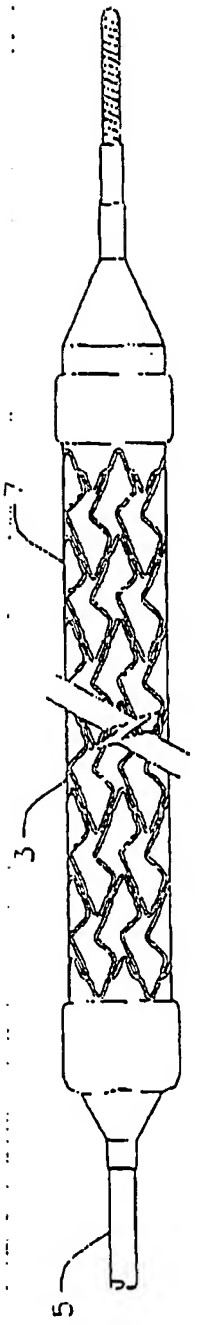

FIG. 1

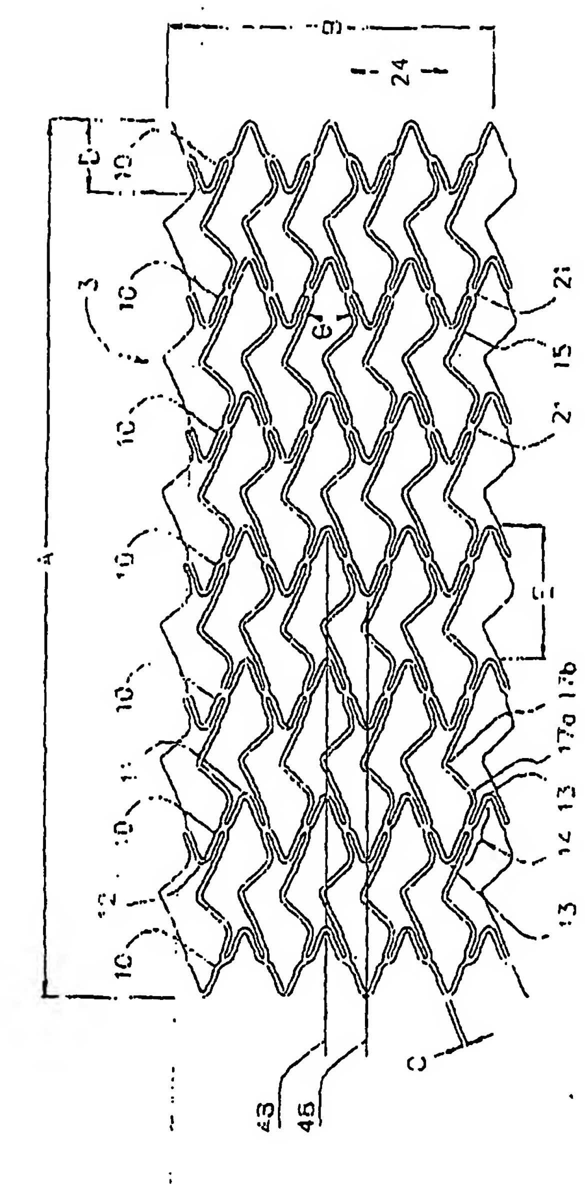

FIG. 2